2:45

## 792-3 Differential Impact of Stent versus PTCA on Restenosis in Large (≥3 mm) and Small (<3 mm) Vessels in the STent REStenosis Study

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To determine the impact of reference vessel size on restenosis (RES) in the multicenter randomized STent REStenosis Study (STRESS), we compared stent (S) vs PTCA in large (≥3 mm by ImageComm quantitative angiographic edge detection methods) and small (<3 mm) vessels.

| | S ≥3 mm N = 102 | PTCA ≥3 mm N = 90 | S <3 mm N = 102 | PTCA <3 mm N = 111 |
|---|---|---|---|---|
| Final % stenosis | 20 ± 10 | 34 ± 11† | 17 ± 13 | 36 ± 17† |
| Acute gain (mm) | 1.86 ± 0.44 | 1.39 ± 0.52† | 1.58 ± 0.44 | 1.10 ± 0.40† |
| Late loss (mm) | 0.71 ± 0.58 | 0.38 ± 0.60** | 0.78 ± 0.55 | 0.49 ± 0.53** |
| Net gain (mm) | 1.11 ± 0.62 | 0.98 ± 0.65 | 0.85 ± 0.59 | 0.63 ± 0.53* |
| RES (≥50% stenosis) | 25.6 | 28.9 | 35.6 | 52.4* |

*P < 0.05, **P < 0.001, †P < 0.0001 compared PTCA with S

For large and small vessels, S (compared to PTCA) had greater acute gain due to lower final % stenosis but S also had greater late loss. Nevertheless, net gain was still greater in S pts resulting in lower RES (vs PTCA). Late angiographic responses to S and PTCA were different in large and small vessels; S had similar late loss irrespective of vessel size, whereas PTCA had less late loss in ≥3 mm vessels which partially neutralizes the acute gain benefit of S. Thus, although RES was generally lower in ≥3 mm vessels, there was little difference among S and PTCA pts. In <3 mm vessel, absolute RES was higher and there was a marked difference in RES between S and PTCA. Importantly, late clinical events showed a similar differential response; target lesion revascularization (CABG or repeat PTCA) was similar for S and PTCA in ≥3 mm vessels (15 vs 13%, NS) but in <3 mm vessels was lower in S pts (22 vs 32%, P = 0.1). *In conclusion:* Data from STRESS indicate that S had a greater impact on lowering RES and increasing clinical benefit in smaller (<3 mm) vs larger (≥3 mm) vessels. Future designs efforts should be directed towards developing a smaller S which can be safely implanted in smaller coronary vessels.

3:00

## 792-4 Three Years Clinical and Quantitative Angiographic Follow-up After the Palmaz-Schatz Coronary Stent Implantation

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Despite its proven efficacy in reducing restenosis in selected lesions, one of the greatest uncertainties of coronary stenting is longer-term results associated with permanent placement of metallic prosthetic devices. To evaluate efficacy and safety in long-term, a prospective serial angiographic study at 6 months (mos), 1 year (yr) and 3 yrs was designed. Between June 1990 to July 1991, single Palmaz-Schatz stent implantation for native coronary arteries was successful in 94 patients (pts) (age: 63 ± 9, male 77%, multivessel disease: 49%) or 97 lesions (les) (LAD: 51%, RCA: 34%, Cx: 7%, LMCA: 8%, restenotic lesion: 54%, bail-out use: 24%). At 3 yrs, 93% of pts were alive, 88% free from death/MI/CABG and 79% free from death/MI/CABG/target lesion revascularization (TLR). Six mos follow-up angiography (FUA) was performed and cine films were available in 88 pts (94%). Nine pts (9.6%) underwent TLR and 3 pts died (cardiac: 1, non-cardiac: 2) within 12 mos. Excluding these 12 pts, 82 pts (85 les) were eligible for longer-term FU. FUA at 1 and 3 yrs was performed in 73 pts (89%), and 49 pts (60%), respectively. CAAS II was used for quantitative analysis.

| | Pre | Post | 6 mos | 1 yr | 3 yrs |
|---|---|---|---|---|---|
| N of les | 52 | 52 | 52 | 52 | 52 |
| Interval (days) | – | – | 193 ± 21 | 374 ± 24 | 1068 ± 105 |
| MLD (mm) | 1.00 ± 0.42 | 2.56 ± 0.5 | 1.98 ± 0.53 | 1.97 ± 0.52 | 2.12 ± 0.53 |
| Ref (mm) | 3.15 ± 0.58 | 3.42 ± 0.6 | 3.06 ± 0.6 | 3.07 ± 0.56 | 3.12 ± 0.56 |

MLD = minimal lumen diameter, Ref = Interpolated reference diameter

MLD improved between 6 mos and 3 yrs (P = 0.016) and did not change between 6 mos and 1 yr. Clinical events beyond 1 yr was analyzed in pts with or without FUA at 3 yrs. In 49 pts with FUA at 3 yrs, 2 pts (4%) suffered from MI unrelated to the stented les. TLR and PTCA for new les were required in 2 pts (4%) and 9 pts (18%) respectively. In 33 pts without FUA at 3 yrs, 3 pts (9%) died from definite non-cardiac causes and 2 pts (6%) underwent TLR due to angiographic restenosis at 1 yr FUA. *In conclusion*, safety and efficacy of stents appeared to be sustained at 3 yrs.

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## 792-5 Three Year Follow-up After Intracoronary Stent Implantation

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To identify predictors of long-term success following intracoronary stenting, we analyzed clinical outcome in 65 consecutive patients who electively received Palmaz-Schatz stents at least 3 years prior to analysis. 83 stents were successfully inserted in 63 of 65 patients (97%), of whom 49 (75%) were men and 16 (25%) were women, with a mean age (±SD) of 59 ± 9 years. 18 patients (28%) were diabetic. 16 patients (24%) required more than one stent. Indications for stenting included restenosis following prior PTCA (52%) and lesion complexity (43%). 10 patients (15%) received stents in saphenous vein grafts.

Demographic, clinical, and procedural predictors of survival and event-free survival at a mean follow-up of 39 ± 17 months were analyzed. Event-free survival was defined as survival without MI, CABG, PTCA at the stent site, or recurrent target vessel ischemia. Survival and event-free survival at 3 years were 86% and 54%, respectively. Predictors of decreased long term survival ($p < 0.05$) included diabetes, and a high angina score (Canadian Heart Class 3–4) at 6 and 12 months following stenting. Predictors of decreased event-free survival ($p < 0.05$) included smaller balloon size at implantation, greater number of stents at the primary lesion, and high angina score at each follow-up interval. Freedom from adverse events by 6 months following stenting correlated with long term success. 35 of 44 patients (80%) with event-free survival at 6 months remained event-free at follow-up. During follow-up, 17 patients (27%) developed symptomatic stent restenosis, requiring primarily early revascularization; 18 patients (28%) developed symptomatic stenoses in other vessels, requiring primarily late revascularization.

*We conclude that:* (1) long term survival after stenting is excellent; (2) the need for late revascularization is dictated primarily by disease progression in non-stented vessels; and (3) long-term success of stenting is predicted by freedom from adverse events at 6 months.

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## 792-6 Late Lesion Regression within the Gianturco-Roubin Flex-Stent

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The late angiographic outcome of the Gianturco-Roubin (GR) intracoronary stent is not well defined. To investigate serial changes within the stent, we studied 13 patients (9 men, 4 women; mean age 63) status-post GR stenting, who had acute, 6-month, and chronic (C) (>12 month) angiographic follow-up without intervening PTCA. Single stents were inserted in 11 patients and double stents in two. Average time to chronic follow-up was 21 months. Electronic calipers were used to determine pre, post, 6-mo, and chronic stent and coronary dimensions, which included MLD (minimum lumen diameter), % sten (% diameter stenosis), and REF (reference dimension). Data are expressed as mean ± 1 SD.

*Results:*

| | MLD (mm) | % Sten | REF (mm) |
|---|---|---|---|
| Pre | 0.95 ± 12 | 69 ± 6% | 2.8 ± 0.17 |
| Post | 2.3 ± 0.16 | 20 ± 5% | 2.9 ± 0.14 |
| 6 mo | 1.6 ± 0.15 | 39 ± 6% | 2.6 ± 0.13 |
| C | 2.1 ± 0.13* | 23 ± 4%* | 2.7 ± 0.15 |

*P < 0.05 C vs. 6-mo

No patient had a significant decline in MLD or an increase in % stenosis at C vs. 6 months. Five had a greater than 50% increase in MLD at C.

*Conclusion:* Long term follow-up demonstrates late lesion regression, which is sometimes dramatic within the GR stent. These data have important clinical implications and suggest that coronary arteriography at 6-months may underestimate the chronic angiographic benefit of the intracoronary Gianturco-Roubin Flex-Stent.